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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Minneapolis District Office
Central Region
212 Third Avenue South
Minneapolis, MN 55401
Telephone: (612) 334-4100
FAX: (612) 334-4134

January 16, 2004

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 04 – 13

Richard A. Linden
President and Chief Executive Officer
Merge Technologies, Inc.
1126 S. 70th Street, Suite S107B
Milwaukee, Wisconsin 53214

Dear Mr. Linden:

An inspection of your medical device manufacturing facility was conducted on November 17-19, 2003. The inspection revealed that your digital image communications and storage devices for radiology are adulterated within the meaning of Section 501(h) of the Federal Food, Drug and Cosmetic Act (the Act), in that the methods used in, or the facilities or controls used for manufacturing, packing, storage, or installation are not in conformance with the Quality System Regulation, Title 21, Code of Federal Regulations (CFR), Part 820.

The deviations are as follows:

1. Failure to document changes to a specification [21 CFR 820.70(b)].

2. Failure to conduct audits according to established procedures to assure that the quality system is in compliance with the established quality system requirements and to determine the effectiveness of the quality system [21 CFR 820.22].

3. Failure to analyze sources of quality data to identify existing and potential causes of nonconforming product or other quality problems [21 CFR 820.100(a)(1)].

4. Failure to submit relevant information on identified quality problems for management review [21 CFR 820.100(a)(7)].

5. Failure to conduct design reviews according to established procedures [21 CFR 820.30(e)].

6. Failure to establish and maintain procedures addressing incomplete, ambiguous, or conflicting design requirements [21 CFR 820.30(a)].

7. Failure of management with executive responsibility to review the suitability and effectiveness of the quality system at defined intervals [21 CFR 820.20(c)].

This letter is not intended to be an all-inclusive list of deficiencies at your firm. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the Form FDA-483 issued at the conclusion of the inspection may be symptomatic of serious underlying problems in your establishment's quality system. You are responsible for investigating and determining the causes of the violations identified by the Food and Drug Administration (FDA). You also must promptly initiate permanent corrective and preventive action on your quality system.

Federal agencies are advised of the issuance of all Warning Letters regarding medical devices so that this information may be taken into account when awarding contracts. Additionally, no premarket submissions for Class III devices to which the Quality System/Good Manufacturing Practice deficiencies are reasonably related will be cleared or approved until the deficiencies have been corrected. Also, requests for export certificates to foreign governments will be refused until the violations related to the subject devices have been corrected.

You should take prompt action to correct these violations and to establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action being initiated by FDA without further notice. These actions include, but are not limited to, seizure, injunction and/or civil penalties.

Please notify this office in writing within 15 working days from the date you receive this letter of the specific steps you have taken to correct the violations. For corrections that you cannot complete within 15 working days, state the reason for the delay and your timeframe for completion. We also ask that you provide documentation of the corrections as they are made and that you explain your plan for preventing these violations in the future.

Please send your reply to Compliance Officer Judy E. Heisick at the address on the letterhead.

Sincerely,

W. Charles Becoat
Director
Minneapolis District

JEH/ccl